Anti-Decubitus
Air Alternating Pressure Mattress System
Operation Manual

Coziny 100/ 200/ 300

Incubator/ Baby Cot/ Baby Crib

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Carilex Medical GmbH
www.Carilex.de

English

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Congratulations and thank you for purchasing this Carilex anti-decubitus mattress system. PLEASE READ THIS OPERATION MANUAL CAREFULLY BEFORE SETTING UP AND USING THE DEVICE.
Pay special attention to the warnings and other safety information. Use genuine Carilex components are essential for optimal performance. If you do not fully understand all the instructions, safety precautions, and warnings, do not use this device. In case you have questions, please contact your local Carilex distributor.

English

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1.0 Indications

Attention! Please read enclosed document thoroughly

CE Declaration of Conformity to Medical Device Directive

International Electronics Approval

IPX0 Do not immerse power unit in liquid or spray liquids directly on power unit

Type B Equipment

Indications

This air alternating mattress system is designed for patients who endure pressure ulcer and potential patients who wish to reduce the likelihood of pressure ulcer. This device is intended to treat and prevent pressure ulcers by facilitating blood circulation and decreasing pressure of each tissue's contact area. Always consult a physician or health professional before using this mattress system.

Contraindications

Certain patient conditions are not suitable for using this type of device such as fracture of instable vertebrae and illness of instable vertebrae. Always consult a physician or health professional before using this device.

The use of this system does not replace the regular repositioning, monitoring, and nursing of the patient.

2.0 Safety Precautions

(1) To ensure proper operation, please inspect and verify all parts are setup properly and anchor securely. Do not place anything on top of the power unit. Make sure power cord is underneath bed frame and free from hazard.

(2) It is recommended to limit bed linens to a single layer in order to allow the moisture escape efficiently through the coverlet. Only "breathable" incontinent pads are recommended for use with this mattress system.

(3) Avoid using this device near open flames, lighters, or cigarettes. Flammability hazard exists. This device draws air from the surrounding. Thus, cigarette smoking may damage internal component.

(4) This system should disinfect thoroughly between patients to avoid cross contamination.

(5) Verify patient weight does not exceed bed frame, bed rails, and this mattress system's weight capacity.

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3.0 Warnings

(1) Use this mattress with proper side rails to ensure the gap between the side rail and top of the mattress is small enough to prevent patient from getting his or her head or neck into the gap. Fail to do so could result in serious patient injury.

(2) DO NOT disassemble the power unit if you are not a qualified technician. Please contact your local distributor for all service.

(3) This product is NOT AP/ APG protected.

(4) Re-position the patient regularly is still necessary when using this mattress.

(5) Operating, transportation, and storage conditions:

Temperature: 5℃ - 40℃
Humidity: 15% - 60%

CAUTION: ENSURE THAT THERE ARE NO PROTRUDING OBJECTS, SHARP POINTS OR BED SPRINGS UNDER THE MATTRESS AS THESE COULD PUNCTURE THE AIR CELLS.

4.0 System Package

Power Unit Package

* Power unit x 1
* Power cord x 1
* Operation manual x 1

Mattr ess Package

Mattress unit with coverlet x 1

5.0 Features

Control Panel Features

See Figure 5a on page 5.

power LED

The green power LED will light when the main power rocker switch on the right side panel is turned on

alarm LED

This low pressure alert notifies medical staff the mattress has insufficient pressure. Audible alarm will sound for 15 seconds at each cycle and the indicator will stay on until the problem has been solved.

pressure monitoring LED

Power unit features an integrated pressure senor which can monitor the mattress' internal pressure 24 hour to achieve optimal internal pressure and to ensure maximum pressure relief. LED indicates the system is monitoring the mattress' internal pressure while the compressor is inflating.

Comfort Knob

Simply turn the knob from min. to max. to adjust the mattress internal pressure. The scale is only an approximation. Please adjust the pressure setting if the mattress is too soft or firm to suit each patient's comfort. Caregivers should always perform a hand check by placing their hands underneath patient's pelvis area to check if there is sufficient air support to ensure the patient is not bottoming out.

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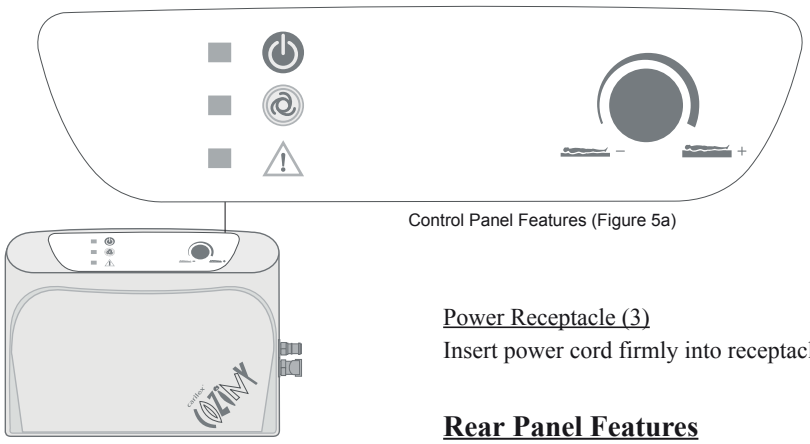
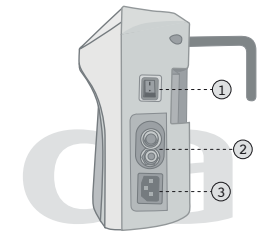
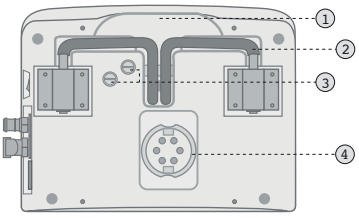


Control Panel Features (Figure 5a)



Right Side Panel Features (Figures 5b)



Right Side Panel Features (Figures 5c)

Right Side Panel Features

See Figure 5b

Rocker Switch (1)
Power unit's main power switch.

Couplers (2)
Quick release couplers are used to secure mattress air hoses to power unit.

Power Receptacle (3)
Insert power cord firmly into receptacle.

Rear Panel Features

See Figure 5c

Convenient Handle (1)
It provides additional gripping surface for user to carry the power unit.

Hanging Hooks (2)
Hanging hooks are designed to hang the power unit on almost any foot board.

Fuse (3)
Fuse holder can be opened for maintenance.

Air Filter and Filter Cap (4)
Carilex recommends that the filter to be clean or replace once a month to ensure optimal performance of the power unit.

6.0 Mattress and Power Unit Installations

(1) Place Carilex mattress on top of the original mattress with the logo at foot end. Secure the mattress by using elastic straps for Coziny 200 and 300 if needed. Please verify all bed

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functions are working properly without interference before proceeding to the next step.

(2) Secure the power unit onto the foot board using hanging hooks.

(3) Firmly connect the mattress' air hose couplings to the quick release couplers on the power unit's air outlet.

(4) Plug the power unit into a wall outlet and turn on the main power rocker switch on the right side panel to inflate the mattress system.

(5) Turn the comfort knob on the power unit's control panel to maximum setting to shorten the initial inflation time if needed.

(6) Wait for approx. 15 minutes or less for the mattress to inflate fully.

7.0 Program Settings

(1) Center the patient on the mattress. Adjust the mattress' internal pressure according to the patient weight by using the comfort knob on the control panel of the power unit. If the patient feels the mattress is too soft or firm, increases or decreases the mattress' internal pressure by fine turning the comfort knob one increment at a time and wait for the system to stabilize before making another change until a comfortable state is achieved.

(2) Caregivers should always perform a hand check by placing their hands underneath patient's pelvis area to check if there is sufficient air support to ensure the patient is not bottoming out.

(3) **IMPORTANT:** TUCKING THE SHEET IN TIGHTLY REDUCES THE EFFECTIVENESS OF THE SYSTEM.

8.0 Patient Transfer and Transport

Transfer

It is recommended to have the mattress system at maximum weight setting during transfer. Make sure the bed is secured before proceeding.

Transport

If a transport occasion comes up, two options are available: (1) Detach the mattress' air hose couplings from the power unit's quick release couplers and connect the two air hose couplings together to retain air in the mattress and the mattress will stay inflated for approx. 2 hours. (2) Unplug the power unit's power cord from the wall outlet and the mattress should stay inflated for approx. 40 - 50 minutes. To resume normal operation, please follow 7.0 Program Setting.

9.0 Cleaning Instruction

Air mattress and power unit must be cleaned thoroughly between patients to

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avoid cross contamination. The following is a suggested guideline, but local infection control policies should be followed as well.

Regular cleaning can be performed at bedside with disinfectant and water followed by drying with a clean dry cloth. Use only mild detergents and water to clean the coverlet and the mattress. Any appropriate NON-PHENOLIC cleaning agent may be used for heavy soiling with urine, blood or other body fluids. Please ensure air mattress and coverlet are completely dry before letting the patient laying on the surface again.

The recommended wash temperature is 71℃. At 95℃ the shrinkage rate is 1% higher and the color might run insignificantly.

Do not use electric or tumble dryers.
Do not iron.

WARNING! Always unplug the power unit before cleaning. Routine cleaning of power unit can be done by wiping down with damp cloth using disinfectant and water. Never spray liquids directly on the unit itself.

10.0 Routine Maintenance

Remove air filter from the real panel of the power unit by opening up the filter cap to clean or replace the air filter. Inspect the filter for dirt or dust and clean it with mild soap and water. Reinsert the dried air filter after cleaning and ensure the cap is secure. Replace with genuine air filter once a year is recommended and compressor every two year is strongly suggested to prolong system lifetime.

Only disinfected and dry systems are to be stored. Disconnect the air hoses from the power unit. Roll up the mattress starting from head end and working down toward the foot end. Use the straps to fix it.

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11.0 Troubleshooting

Problem	Inspection Procedure	Possible Solutions
1. Power unit does not function.	Check if power cord is firmly plugged into wall outlet.	Secure power cord into wall outlet.
	Check if power switch is in ON position.	Turn power switch to ON position.
	Check if power surge shuts down power unit.	A power surge may overload the circuitry temporarily. Turn the unit off and check the fuse for damage. Turn the unit ON again with normal procedure.
	Make sure there is no power failure.	
	Power unit does not respond to possible solutions.	Please contact your authorized local distributor for assistance.
2. Low pressure alert does not go out in 30 sec. after systems start.	Possible control failure.	Please contact your authorized local distributor for assistance.
3. alarm LED is lit during operation.	Check if there is leakage in air tubes* or air cells.	Please contact your authorized local distributor for assistance.

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4. Power unit is working, but mattress replacement is not inflating. Or/and Bottoming out is occurring. Or/and Patient leaves a deep dent at the contact area which does not return back to its original shape (worn down by the patient)	Verify if CPR latch is properly inserted.	Connect CPR latch securely.
	Check if mattress' air hose couplings are properly connected to power unit's quick release couplers.	Secure air hose couplings firmly into place.
	Verify if patient weight setting is correct.	Increase or decrease weight setting until appropriate pressure is reached.
	Inspect air filter for dust.	Clean or replace air filter.
	Lift mattress coverlet up to check if air cells are connected correctly.	Make sure all air cells are properly linked to air supply.
	Lift mattress coverlet up to check if air tubes are kinked or obstructed.	Check and adjust air tubes' positions.
	Check if air cells are cut or cracked.	Replace with genuine spare parts or contact your local distributor.
5. Patient is not getting pressure relief due to system failure (reddening of skin).		Contact your physician and/ or nursing service immediately.

* Air tube is referring to the mean of directing air flow from the power unit to each individual air cell.

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12.0 Returns for Service

This device is not self-serviceable. Service and repair must be performed by an authorized technician or representative. All returned device must be cleaned and disinfected prior to shipping. Unsanitary or soiled systems will be returned without servicing.

13.0 Warranty

Carilex Medical GmbH warrants the product to be free from defects from the date of purchase. Please inspect all accessories when you purchase our product. If there is any damage or missing accessories when you receive the product, please ask for a replacement from your local distributor within three days of purchase.

The warranty periods for Carilex products are according to the regulations in your country, the minimum period is 1 year from date of purchase for the power unit and 1 year for the mattress and the coverlet. The warranty coverage of any Carilex product is contingent up on its purchase from an authorized dealer. Warranty for any product in the Carilex product line will be honored by the official distributor in your country.

Warranty coverage will not be extended to any product on which the production lot number has been removed or defaced, on which repair has been attempted by any person or agency not authorized by Carilex or if in the sole opinion of Carilex that the system shows evidence of tampering, abnormal or unreasonable abuse, negligence, accident or operation without regard for the restrictions specified in the instructions which accompany the system. This warranty does not cover normal maintenance such as cleaning, adjustment, lubrication, and updating of equipment or parts. If the damage is result from improper operation, a reasonable service fee and part cost will be charged.

The warranty stated above is the only warranty made and is in lieu of all other warranties whether expressed or implied, including any warranty of merchantability or fitness for a particular reason. Carilex Medical GmbH will not be liable for consequential or incidental damages or any kind.

14.0 Product Specifications

The Coziny series contains three models for different sleeping surfaces: Coziny 100 for incubator, Coziny 200 for baby cot, and Coziny 300 for baby crib. Please use the appropriate model that best suit your need.

Mattress Dimension (MSR215/ 216/ 217)

Coziny 100 (MSR215): 68 x 38 x 2 cm
Coziny 200 (MSR216): 75 x 49 x 7 cm
Coziny 300 (MSR217): 140 x 70 x 8 cm

Number of Air Cells

Coziny 100: One piece pad with 46 air cells
Coziny 200: 20 air cells
Coziny 300: 39 air cells

Power Control Unit Dimension (SR368)

29.5 x 22.5 x 12.0 cm

Material

Power Unit - ABS fire retardant UL
Mattress Cell - 100% nylon with TPU lamination
Coverlet -Dartex 100% nylon with PU backing

Power Input

AC 100 - 120V/ 50 - 60 Hz
AC 220 - 240V/ 50 Hz

Power Consumption

Normal Operation: Max 10W

Power Control Unit Weight

2.5 kg

Power Cord

H05VV-F3x1.00mm^2

Fuse Rating

T1A/ 250V

Operating & Transportation & Storage Conditions

Temperature: 5℃ - 40℃
Humidity: 15% - 60%

Electrical Classification

Class I Type B, double insulated with or without functional ground wire.
IPX0, do not immerse power unit in any liquid or spray any liquids directly on the power unit.
This system is not AP/ APG protected.
Continuous operation.

Agency Approval

EN60601-1, EN60601-1-2,
EN61000-3-2, EN61000-3-3, UL2601-1

Electromagnetic Compatibility

EN60601-1-2:1993

Maximum Weight Capacity

Coziny 100: 3.5 kg
Coziny 200: 6 kg
Coziny 300: 25 kg

Carilex reserves the right to change prices or design parameters and specifications without incurring any liability in connection with such modifications.

15.0 Environmental protection

The instructions for use shall:
- identify any RISKS associated with the disposal of waste products, residues, etc. and of the ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE; and
- provide advice on minimizing these RISKS.

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SUZRIC ENTERPRISE CO., LTD.

CE EU Declaration of Conformity CE

according to the Medical Device Directive 93/42/EEC

Product：	Coziny 100/200/300
Type Designation：	Support Surface
Model：	Power Unit- SR368
	Mattress-
	Coziny 100: MSR215
	Coziny 200:MSR216
	Coziny 300:MSR217
Classification：	I For Annex IX, MDD

We herewith declare that the above mentioned product concerned meet the provisions of the following EC Council Directive and Standards：

General Applicable Directive：Medical Device Directive 93/42/EEC

Standards： EN 60601-1
EN 60601-1-2
EN 980
ISO 13485
ISO 14971

Responsible for making this declaration is：

☒ The Manufacturer

☐ The Authorized representative in the EU (if applicable)：

Manufacturer's Name：	Suzric Enterprise Co., Ltd.
Manufacturer's Address：	No. 77, Keji 1st Rd., Guishan Township, Taoyuan County, Taiwan (R.O.C)
	Tel：+886-3-3287882 / Fax：+886-3-3288622

Person responsible for making this declaration

Name, Surname	Suzanne Wang
Position/Title	President

Suzric Enterprise Co., Ltd. Taipei Taiwan

Taipei July. 28, 2011

(Company stamp and legal signature)

For Class I Products Only

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Turmbergstr. 9A, D-76227 Karlsruhe, Germany
Tel:+49(0)721 16 19 835 · Fax:+49(0)721 16 19 836
Email: info@carilex.de
Website: http://www.carilex.de